DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
Rockville, Maryland 20852

[June 7, 2010]

Jacquelyn L. Goldberg, J.D.
Head, Central IRB Initiative
National Cancer Institute
6130 Executive Blvd., Room 6102
Rockville, Maryland 20852

Re: Secretary's Determination on the Research Protocols:
COG Protocol ASCT0631: A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation *and*
COG Protocol ASCT0631D: A Comparison of Acute and Long-Term Toxicities in Bone Marrow Donors with and without G-CSF Treatment Prior to Harvest: A Companion Study to ASCT0631
Formerly:
COG Protocol ASCT0631: A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation

Study Chair: Stephan A. Grupp, MD
Principal Investigator: Eric Sandler, MD
NCI Grant No. PASCT0631#R02PAPP01

Dear Ms. Goldberg:

Thank you for the National Cancer Institute's (NCI's) Central Institutional Review Board (CIRB) minutes, approved revised protocols, and approved revised parental permission forms for the Children's Oncology Group (COG) protocols entitled, *COG ASCT0631: A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation* and *COG ASCT0631D: A Comparison of Acute and Long-Term Toxicities in Bone Marrow Donors with and without G-CSF Treatment Prior to Harvest: A Companion Study to ASCT0631*. As you know, the Nemours Oncology IRB forwarded the protocol, *COG ASCT0631: A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation*, to the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) for consideration pursuant to requirements of the HHS regulations at 45 CFR 46.407 and the FDA regulations at 21 CFR 50.54, respectively.

Based on correspondence from COG and the NCI's CIRB, we understand that a separate protocol has been developed for the donors participating in this research study to address the six stipulations outlined in OHRP's and FDA's letter of June 11, 2009. On behalf of the Assistant Secretary for Health, Department of Health and Human Services (HHS), and the Commissioner, FDA, OHRP finds that all of the stipulations have been met in the revised protocols, entitled, *COG ASCT0631: A Phase III Randomized Trial of G-CSF Stimulated Bone Marrow vs. Conventional Bone Marrow as a Stem Cell Source in Matched Sibling Donor Transplantation* and *COG ASCT0631D: A Comparison of Acute and Long-Term Toxicities in Bone Marrow Donors with and without G-CSF Treatment Prior to Harvest: A Companion Study to ASCT063*1.

The research in the revised protocols conforms with the requirements of the HHS regulations at 45 CFR 46.407 and the FDA regulations at 21 CFR 50.54, and now may proceed, relying upon the HHS support provided by the NCI, National Institutes of Health under grant number PASCT0631#R02PAPP01.

This concludes the 45 CFR 46.407 and 21 CFR 50.54 review process. It is the responsibility of the NCI CIRB to oversee the conduct of this research and to conduct continuing review of this protocol.

We are sending a similar notification to the Nemours Oncology IRB. Please do not hesitate to contact us with any questions. Thank you for your continuing commitment to the protection of human subjects.

Sincerely,

[/s/ J. Menikoff, M.D., J.D.]

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections

cc:
Dr. Amy Patterson, NIH
Ms. Sarah Carr, NIH
Dr. Joanne Less, FDA
Dr. Dianne Murphy, FDA
Dr. Robert Nelson, FDA
Dr. Sara Goldkind, FDA
Dr. Stephan Grupp, Children's Hospital of Philadelphia
Dr. Tim Wysocki, Nemours Oncology IRB
Dr. Edward E. Bartlett, OHRP